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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/530,464	NYLESE, TARA	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2-9 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 10-21* is/are rejected.

7)☒ Claim(s) *1 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The amendments to claims 1, 10 – 13, 15, 16, and 20 are acknowledged.

Currently, claims 1 and 10 – 21 are pending and under examination.

Election/Restrictions

Applicant's further traversal of the lack of unity requirement has been considered, but is still not considered persuasive. The traversal is on the ground(s) that the lack of unity is in error because the cited reference of Lu (US 6,203,757), which teaches a test device that tests for multiple analytes, does not teach Applicant's "special" technical feature of a test device that comprises a detection of different concentrations of an analyte, wherein the device contains a plurality of regions capable of generating a signal in response to a minimum level of analyte in the sample. Lu teaches a device that comprises a substrate (23), a plurality of membranes (26a-e) in the form of test strips, each containing a test or capture zone, which is responsive to an analyte (target chemical) (see Figures 2 and 3; and columns 6 – 7, in particular). Further, the device can be utilized to test for only one analyte, wherein each test strip comprises a detection of a different concentration of the analyte in order to establish a semi-quantitative analysis (see claims 1 and 2, in particular). However, Lu does not teach an embodiment wherein different concentrations of the analyte are detected through only one test strip, wherein the plurality of regions are contained on a single test strip. This feature, i.e. Applicant's "special" technical feature, is still considered known in the art as

presented in the previous office action through the cited reference of Boehringer et al. (WO 98/39657). Thus, the Applicant's "special" technical feature which links Groups I – IV is known in the art and therefore, lack of unity exists because the inventions do not form a general inventive concept, as they do not share a common special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Withdrawn Objections and Rejections

All previous objections to the specification and claims are withdrawn in view of Applicant's amendments filed July 10, 2006.

The previous rejections of claims 1, 10 – 13 and 20 under 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's amendments filed July 10, 2006.

Claim Objections

Claims 1 and 13 are objected to because of the following informalities:

Claim 1, line 8, recites the phrase "one or more regions of the first test," which appears to be missing the term "device" after "test."

Claim 13 is objected to because it is dependent on itself.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 10 – 16 and 19 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer et al. (WO 98/39657).

Boehringer et al. teach a lateral flow assay method for monitoring changes in analyte concentration (level) in a sample (source), the method comprising: defining multiple measurable distinguishable sensitivity level each indicative of a different amount, i.e. concentration, of analyte in the source;

providing a first test matrix (unit) including a first capture line (region) thereon responsive to the presence of analyte in the sample at a first of the sensitivity levels;

providing a second test matrix (unit) including a first capture line (region) thereon responsive to the presence of analyte in the sample at a second of the sensitivity levels;

providing a first sample from one source;

bringing the first sample into contact with the first test matrix to provide the first capture line thereon an opportunity to indicate the presence of analyte in the sample at at least the first level;

providing a second sample from the same source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second test matrix to provide the first capture line thereon an opportunity to indicate presence of analyte in the sample at at least the second level (see Figure 3; and p4, lines 22-38; p5, lines 1-2; p6, lines 26-34; p13, lines 27-37; p14, lines 6-27; p15, lines 29-32; p23, lines 7-25; p29, lines 35-38; p30, lines 1-21; Example 6 on p48; and "Multiple lane lateral flow test devices" on p52-54).

With respect to Applicant's claims 11 – 13, the first test matrix can include a second capture line responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first test matrix includes providing said second capture region an opportunity to indicate the presence of analyte in the sample at at least the second level, wherein the second capture line is a measurably distinguishable sensitivity level different than the first of the sensitivity levels, or wherein the first and second sensitivity levels are the same (see Figure 3; and p6, lines 1-7; p13,

lines 27-30; p14, lines 6-27; p15, lines 29-32; Example 1 on p39; and Example 6 on p48).

With respect to Applicant's claim 14, the second test matrix includes a second capture line thereon responsive to the presence of the analyte in the source at the first of the sensitivity levels (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; p15, lines 29-32; Example 1 on p39; and Example 6 on p48).

With respect to Applicant's claims 15 and 16, the first and second test matrices can include forming thereon at least three capture lines each responsive to the presence of the analyte in the source at a different of the multiple distinguishable sensitivity levels (see Figure 3; and p6, lines 1-7; p13, lines 27-30; p14, lines 6-27; and p15, lines 29-32).

With respect to Applicant's claim 19, the step of defining the multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the sample is accomplished by forming at least the first capture lines (see Figure 3; and p4, lines 22-38; p5, lines 1-2; and p6, lines 26-30).

With respect to Applicant's claim 20, the method is already discussed above for claim 10, additionally as seen in Figure 3, up to three test units are presented.

With respect to Applicant's claim 21, a substrate 20 is provided to adhere the test units to (see Figure 3).

Claims 10, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kenjyou et al. (US 2004/0096985).

Kenjyou et al. teach a method for monitoring changes in analyte level of a sample source, wherein the method comprises: defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the sample source;

providing a first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels;

providing a second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

providing a first sample from the sample source;

bringing the first sample into contact with the first unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the first level;

providing a second sample from the source on an occasion subsequent to providing the first sample; and

bringing the second sample into contact with the second unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the second level (see Figure 2; and paragraphs [0015], [0019], [0021], [0027], [0059], [0061], [0070], [0076], [0080], [0123], [0131], [0143]-[0145], [0161], [0165], [0189] and [0193]).

With respect to Applicant's claim 19, the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the

source is accomplished by forming at least the first regions (see Figure 2; and paragraphs [0143]-[0145], [0189] and [0193]).

With respect to Applicant's claim 20, , the method is already discussed above for claim 10, additionally as seen in Figure 2, up to five test units are presented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (WO 98/39657) or Kenjyou et al. (US 2004/0096985) in view of Toranto et al. (US 2003/0175992).

The Boehringer et al. and Kenjyou et al. references discussed above both teach methods for monitoring changes in analyte levels in a sample source comprising: providing multiple test devices, each including a plurality of regions, wherein the regions are responsive at a different sensitivity level; bringing a sample from the source into contact with the first of the test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more of the test regions; and subsequently bringing a different sample from the source into contact with a second of

the test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the second test device. However, both references fail to teach the monitoring is of temporal changes in analyte levels or concentration.

Toranto et al. teach a test system for detection of a variety of analytes in saliva. The test system comprises a single device to test for the presence of a particular analyte of interest. The system also includes storage for a multiplicity of test units that can be accessed and used on one or more occasions, e.g. on one or more separate days, weeks or months. The multiplicity of test units allows for individuals to use more than one assay test on a given occasion, for example, to determine if their analyte concentration has increased or dropped over time. This type of test system wherein the test units can be accessed on separate occasions is important for analytes whose concentrations change over time and need to be monitored, such analytes include alcohol, glucose, ketones, cancer markers (e.g. PSA), illicit compounds, caffeine, hormones, and pathogens (see paragraphs [0055], [0056], [0059], [0126], and [0146]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the methods of Boehringer et al. or Kenjyou et al. the use of the separate test units in monitoring of temporal changes in analyte concentrations as taught by Toranto et al. because Toranto et al. teaches the benefit of including multiple test units in a system in order to allow individuals to use more than one assay test on a given occasion, for example, to determine if their analyte concentration has increased or dropped over time, which is important for analytes

whose concentrations change over time and need to be monitored, such analytes including alcohol, glucose, ketones, cancer markers (e.g. PSA), illicit compounds, caffeine, hormones, and pathogens.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (WO 98/39657) in view of Cole (US 6,656,745).

Boehringer et al. further fail to teach that at least one of the three regions of the first matrix (unit) is responsive to substantially the same level of analyte as one of the three regions in the second matrix (unit), or that each of the regions of the first matrix is responsive to substantially the same level of analyte as one of the regions of the second.

Cole teaches a device and method for multi-level, semi-quantitative immunodiffusion assay. The device utilizes a plurality of binding zones wherein the concentration of binding agent immobilized determines a sensitivity of a given binding zone. Individual binding zones can be reactive for pre-determined levels of analyte in a sample, i.e. each binding zone has a specified concentration of binding reagent. Therefore, the binding zones allow for testing of an analyte over a broad range of concentration. The device normally involves a three-binding zone device or "tri-level test." The number of levels can be tailored in combination with the concentration of binding reagents to alter the sensitivity of the semiquantitative analysis depending on the particular application or desired precision. The device can detect for the presence or absence of the analyte, i.e. by determining trace levels of the analyte, as well as the

semiquantitative amount of analyte present. Thus, the device is beneficial to screen for detection and progress of a particular medical condition, e.g. one threshold level can indicate that the condition is at a preliminary stage, whereas another threshold amount can indicate that the condition is in an advanced state. Such devices are beneficial for testing of analytes that occur in a range, such as prostate specific antigen (PSA) or pregnancy hormone (HCG), whose concentration range determines what, if any medical action is necessary (see column 5, lines 16-67; column 6, lines 7-48; and column 7, lines 16-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include substantially the same sensitivity level in one of the three regions found in both the first and second matrices of Boehringer et al. because Cole teaches the benefit of using a "tri-level test" wherein one of the three regions tests for trace levels of the analyte in order to determine if the analyte is in fact present or absent within the sample. It also would have been obvious to create the regions of the first unit to be responsive to substantially the same level of analyte as only one of the regions of the second in order to allow for testing of an analyte over a broad range of concentration as taught by Cole because Cole teaches the benefit of semiquantitative testing of analytes that occur in a range, such as prostate specific antigen (PSA) or pregnancy hormone (HCG), whose concentration range determines what, if any medical action is necessary.

Response to Arguments

Applicant's arguments filed July 10, 2006 have been fully considered but they are not persuasive. There are two main arguments presented by Applicant:

1) Neither the Boehringer et al. or the Kenjyou et al. references teach providing multiple test devices; and

2) Neither the Boehringer et al. or Kenjyou et al. references teach providing a second sample from the source on an occasion subsequent to providing the first sample.

With regard to Applicant's first argument, both Boehringer et al. and Kenjyou et al. teach providing first and second test units, wherein each unit contains at least one capture or detection zone that indicates the presence of the analyte in a sample at a certain level. The "units" of Boehringer et al. are presented most accurately in Figure 3 of the reference, wherein each "unit" comprises a test strip containing at least one capture zone, wherein the strips are connected to a main backing. Similarly, Kenjyou et al. teach a plurality of test "units" that are each connected together (see Figures 2 and 7). However, Applicant's recitation for the first and second "test units" in claims 10 and 20 do not teach away from these embodiments for the test units taught by Boehringer et al. and Kenjyou et al. Therefore, both Boehringer et al. and Kenjyou et al. anticipate the first and second test units of Applicant's claims 10 and 20.

With regard to Applicant's second argument, both Boehringer et al. and Kenjyou et al. teach providing first and second samples to the plurality of test units, wherein the samples can be provided from the same source at subsequent occasions. Applicant

does not specify what exactly is meant by " an occasion subsequent," and therefore, as long as both references teach applying the sample to the units one at a time, this anticipates a "subsequent occasion." With respect to the Boehringer et al. reference, the embodiment presented in Figure 3 allows for a sample to be applied onto each sample receiving pad at a subsequent time in order for the concentration of an analyte in a sample to be determined (see Figure 3; and p29, lines 34-38; p30, lines 1-38; and p31, lines 1-7). With respect to the Kenjyou et al. reference, the embodiment of Figure 2 allows for a sample to be applied into the inlet of each unit separately, i.e. on subsequent occasions, in order for the concentration of the analyte in the sample to be determined (see Figure 2; and paragraphs [0123] and [0143]-[0145]).

Therefore, the references of Boehinger et al. and Kenjyou et al. anticipate Applicant's claims 10 and 20.

Applicant's subsequent argument over the Toranto et al. reference that was used as a secondary reference in the first 35 U.S.C. 103(a) rejection was considered, but again was not found persuasive. The Boehringer et al. and Kenjyou et al. references, as discussed above, teach the limitations of a test unit including a plurality of regions, wherein each region is responsive at a different sensitivity level. However, the references do not teach providing multiple unitary test devices in order to test for temporal changes of analyte levels in a source. The Toranto et al. reference, as also noted by Applicant, does not teach a test device with a plurality of regions of different sensitivity; however, the Toranto et al. reference was not presented for this limitation as

it was already discussed as being taught by the Boehringer et al. and Kenjyou et al. references. Toranto et al. teach a test system for detection of a variety of analytes in saliva. The test system comprises a single device to test for the presence of a particular analyte of interest. The system also includes storage for a multiplicity of test units that can be accessed and used on one or more occasions, e.g. on one or more separate days, weeks or months. The multiplicity of test units allows for individuals to use more than one assay test on a given occasion, for example, to determine if their analyte concentration has increased or dropped over time. This type of test system wherein the test units can be accessed on separate occasions is important for analytes whose concentrations change over time and need to be monitored, such analytes include alcohol, glucose, ketones, cancer markers (e.g. PSA), illicit compounds, caffeine, hormones, and pathogens (see paragraphs [0055], [0056], [0059], [0126], and [0146]). Therefore, Toranto et al. provide motivation for including a plurality of unitary test devices, such as those taught by Boehringer et al. and Kenjyou et al., in order to monitor changes in analyte concentrations over time.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jackie DiRamio
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Art Unit 1641

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